No. 89-243

IN THE

SUPREME COURT OF THE UNITED STATES

October Term, 1989

ELI LILLY, AND COMPANY

Petitioner,

v.

MEDTRONIC, INC.

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

MEMORANDUM OF RESPONDENT MEDTRONIC, INC. IN OPPOSITION TO THE MOTION OF PFIZER HOSPITAL PRODUCTS GROUP, INC. AND PFIZER INC. FOR LEAVE TO FILE BRIEF AMICI CURIAE IN SUPPORT OF THE PETITION FOR CERTIORARI

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Respondent Medtronic, Inc. hereby opposes the motion of Pfizer Hospital Group, Inc. and Pfizer Inc. ("Pfizer") for leave to file their brief of *amici curiae* in support of the petition of Eli Lilly and Company for a writ of certiorari.

I. PFIZER'S INTERPRETATION OF *ROCHE* CONTRADICTS PETITIONER'S INTERPRETATION

Pfizer takes the surprising position that the Federal Circuit misread its own decision in *Roche Prods., Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d. 858, *cert. denied,* 469 U.S. 856 (1984). (Pfizer Br. at 4). Although Pfizer argues (Pfizer Br. at 3) that the *Roche* decision was strictly limited to drugs and had no

precedential effect as to medical devices, Pfizer overlooks the fact that even petitioner Lilly argued below that "*Roche* . . . controls for infringement of non-drug patents" (Lilly Brief on Appeal, at 18). The Federal Circuit agreed:

> Under the *Roche* ruling, infringement would be found for the investigation testing of an infringing medical device even though, under 21 U.S.C. §360e (1982 & Supp. III 1985) of the Federal Food, Drug, and Cosmetic Act, such testing is required to obtain FDA approval to market such devices.
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> * * *
>
> While the claimed subject matter in *Roche* was limited to a drug product, the holding of that case was not so limited. The holding provided an interpretation of the scope of 35 U.S.C. §271(a) without regard to what particular goods might be involved.

(Pet. App. 3a, 6a). Pfizer therefore seeks to substitute its personal interpretation of *Roche* in place of that argued by petitioner and accepted by the court below. In view of this divergence of interpretation, acceptance of Pfizer's brief would not aid the Court in deciding whether the issue raised by petitioner should be heard on its merits.

II. BIOEQUIVALENCY TEST PROCEDURES ARE IRRELEVANT TO THE SCOPE OF 271(e)(1)

Pfizer argues (Pfizer Br. at 5-6) that the exemption in 271(e)(1) was intended solely to effectuate the expedited bioequivalency testing procedures for generic drugs, and therefore the exemption should be construed in light of its narrow purpose. Pfizer observes (Pfizer Br. at 5) that "there were no comparable provisions for abbreviated testing for 'generic' medical devices," and hence the exemption does not reach such devices.

Contrary to Pfizer's assertions, Congress plainly extended the exemption created by §271(e)(1) to products for which there is no expedited bioequivalent testing procedures. Pioneer new drugs are, by definition, not eligible for approval under the

expedited bioequivalency procedures[1] but the developers of such drugs are unquestionably entitled to the exemption of §271(e)(1) for the purpose of developing the safety and efficiency data required by the FDA under Section 505(b)(1) of the FFDC Act, 21 U.S.C. §355(b)(1). Similarly, the 1988 amendment of Section 271(e)(1) added veterinary biological products to the exemption despite the fact that there is no expedited approval procedure available under primary law that regulates them, the Virus-Serum-Toxin Act. 21 U.S.C. §§151-159.

Accordingly, the Federal Circuit has correctly concluded that "no persuasive reason is suggested why Congress would create an exception with respect to . . . drugs only, particularly as medical devices receive the benefit of the companion of the patent term restoration legislation." (Pet.App. 7a). The availability of bioequivalency testing for drugs is not such a reason.

III. PFIZER'S POLICY ARGUMENTS ARE UNSUPPORTED

The record and legislative history further rebut Pfizer's unsupported allegation that "the decision below significantly impedes the availability of new medical devices" (Pfizer Brief at 2). As the record indicates, numerous companies are in the process of developing new cardioverter/defibrillator devices for commercial introduction after the expiration of the Lilly patent.[2] Pfizer seeks to have 35 U.S.C. 271(e)(1) construed so that these

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1. Pioneer new drugs are those which have never before been approved; they must be tested fully for safety and efficacy. Pioneer new drug applications therefore cannot "piggyback" on existing safety and efficacy data submitted in connection with any previously approved drug. Bioequivalency testing is used when a competitor, typically a generic manufacturer, wishes to gain approval for a competing product that is the same as or substantially similar to a drug already approved. In this case, the later applicant for commercial approval may rely upon the original safety and efficacy data, provided data is submitted to show that the proposed new product is a bioequivalent. In either instance, the testing of the drug is clearly within the scope of 271(e)(1), since the exemption of this statute is not limited to bioequivalency testing.

2. In addition to Medtronic, Telectronics and Ventritex indicated to the Federal Circuit that they are also developing new generations of such products.

new devices will be effectively kept out of the commercial marketplace for years *after* the expiration of the Lilly patent. Such a result would give Lilly a *de facto* extension of its patent in addition to the statutory two year extension it has already received.

Contrary to Pfizer's assertions however, it was not Congress' intention to grant medical device patentees statutory patent extensions while permitting them to retain the *de facto* extensions which were effectively established as the result of the ruling in *Roche*. The House Committee report explained:

> It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the expiration date.
>
> Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time and, thereafter, immediate competition should be encouraged.
>
> * * *
>
> Other sections of Title II [of the 1984 Act] permit the extension of the term of a patent for a definite time provided certain conditions are met. There should be no other direct or indirect method of extending patent term.

H.R. REP. NO. 857, Pt. I, at 46. Congress' intention was to establish a fair use exception that would permit limited FDA testing so that such *de facto* patent extensions would not be available:

> In this case the Committee has merely done what Congress has traditionally done in the area of intellectual property law; balance the need to stimulate innovation against the goal of furthering the public interest. Just as we have recognized the doctrine of fair use in copyright, it is

> appropriate to create a similar mechanism in the patent law. That is all this bill does.

H.R. Rep. No. 857(II), 98th Cong. 2d Sess. 30 (1984) (footnote omitted). Congress therefore recognized that FDA regulatory testing "does not have any adverse impact on the patent owner's exclusivity during the life of the patent." H.R. Rep. No. 857(I), 98th Cong. 2d Sess. 46 (1984). As the Judiciary Committee explained:

> The patent holder retains the right to exclude others *from the major commercial marketplace* during the life of the patent. Thus, the nature of the interference with the rights of a patent holder is not substantial.

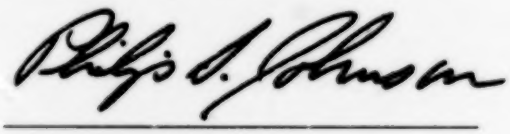
H.R. Rep. No. 857(II), 98th Cong. 2d Sess. 8 (1984) (emphasis added).

The outcome of the present case is not at odds with that envisioned by Congress. In return for the FDA regulatory delay it experienced, Lilly has extended its patent for an additional two years, during which it will sell over 6,000 units and collect over 100 million dollars. Although Medtronic may conduct FDA testing using a limited number of experimental units in the meantime, Lilly has retained the right to exclude others "from the major commercial marketplace".

IV. CONCLUSION

Pfizer has sharply criticized the Federal Circuit's view of the legislative intent, yet has failed to support its contrary interpretation with a single citation to the legislative history. Pfizer's position rests upon an interpretation of *Roche* which is contrary to that taken by both petitioner and the court of appeals. Acceptance of Pfizer's brief would be more likely to confuse the issues raised by Lilly's petition than to assist the Court in deciding whether certiorari should be granted. Accordingly, Pfizer's motion for leave to file its brief should be denied.

Respectfully submitted,



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